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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,833	11/09/2006	Yusuke Nakamura	082368-0039000US	4652

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EXAMINER	
BAUGHMAN, MOLLY E	

ART UNIT	PAPER NUMBER
1637	

MAIL DATE	DELIVERY MODE
11/12/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/529,833	NAKAMURA ET AL.	
	Examiner	Art Unit	
	Molly E. Baughman	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-32* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-3, and 6-12, drawn to a method of diagnosing CML or a predisposition to developing CML by determining a level of expression of a CML-associated gene consisting of CML 1-190 in a patient.

Group II, claim(s) 1, 3-5, 6-12, drawn to a method of diagnosing CML or a predisposition to developing CML by determining a level of expression of a CML-associated gene consisting of CML 191-296 in a patient.

Group III, claim(s) 17 in part and 19, drawn to a method of screening for a compound for treating or preventing CML, comprising selecting a compound that *reduces* the expression level of one or more marker genes selected from the group consisting of CML 1-190.

Group IV, claim(s) 17 in part and 19, drawn to a method of screening for a compound for treating or preventing CML, comprising selecting a compound that *elevates* the expression level of one or more marker genes selected from the group consisting of CML 191-296.

Group V, claim(s) 18 in part, drawn to a method of screening for a compound for treating or preventing CML, comprising selecting a compound that *suppresses the biological activity of the polypeptide encoded* by CML 1-190.

Group VI, claim(s) 18 in part, drawn to a method of screening for a compound for treating or preventing CML, comprising selecting a compound that *elevates the biological activity of the polypeptide encoded* by CML 191-296.

Group VII, claim(s) 20 in part, drawn to a method of screening for a compound for treating or preventing CML, comprising selecting a compound that reduces the

expression level of a reporter gene expressed in a cell/vector system comprising a marker gene when the marker gene is an up-regulated marker gene selected from by CML 1-190.

Group VIII, claim(s) 20 in part, drawn to a method of screening for a compound for treating or preventing CML, comprising selecting a compound that enhances the expression level of a reporter gene expressed in a cell/vector system comprising a marker gene when the marker gene is an down-regulated marker gene selected from by CML 191-296.

Group IX, claim(s) 13-15, drawn to a CML reference expression profile comprising a pattern of two or more genes selected from the group consisting of CML 1-296.

Group X, claim(s) 16, drawn to a method of screening for a compound by contacting compound with a polypeptide encoded by CML 1-296 and detecting the binding activity.

Group XI, claim(s) 21-22, drawn to a kit and array comprising a detection reagent that binds to two or more nucleic acid sequences selected from CML 1-296.

Group XII, claim(s) 23, drawn to a method of treating or preventing comprising administering an *antisense* compound comprising a nucleotide sequence complementary to one of CML 1-190.

Group XIII, claim(s) 24, drawn to a method of treating or preventing comprising administering *a siRNA composition* wherein said composition reduces the expression of a nucleotide sequence selected from the group consisting of CML 1-190.

Group XIV, claim(s) 25, drawn to a method of treating or preventing comprising administering a pharmaceutically effective amount of *an antibody* that binds to a protein encoded by a nucleotide sequence selected from CML 1-190.

Group XV, claim(s) 26, drawn to a method of treating or preventing comprising administering a vaccine comprising a polypeptide encoded by a nucleotide sequence consisting of CML 1-190.

Group XVI, claim(s) 27 and 28, drawn to a method of treating or preventing comprising administering to a subject a compound that increases the expression or activity of CML 191-296, or a compound obtained by the method according to any one of 16-20.

Group XVII, claim(s) 29, drawn to a method of treating or preventing comprising administering to a pharmaceutically effective amount of polynucleotide selected from the group consisting of 191-296.

Group XVIII, claim(s) 30, drawn to a composition for treating or preventing CML comprising a pharmaceutically effective amount of an antisense polynucleotide, or small interfering RNA against a polynucleotide selected from CML 1-190.

Group XIX, claim(s) 31, drawn to a composition for treating or preventing CML comprising a pharmaceutically effective amount of an antibody or fragment thereof that binds to a protein encoded by a gene selected from CML 1-190.

Group XX, claim(s) 32, drawn to a composition comprising a pharmaceutically effective amount of the compound selected by the method of any one of claims 16-20 as an active ingredient, and a pharmaceutically acceptable carrier.

2. The inventions listed as Groups I-XX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the special technical feature of Group I (claim 1), a method of diagnosing CML or a predisposition to developing CML by determining a level of expression of a CML-associated gene in a patient derived biological sample, wherein an increase or decrease of said level compared to a normal control level of said gene indicates that said subject suffers from or is at risk to developing CML, does not provide contribution over the prior art (see Li et al., "cDNA microarray analysis of chronic myeloid leukemia," Intern. J. Hem., 2002, Vol.75, No.4, pp.388-393, of record).

3. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Restriction Subgroups

This application contains claims directed to the following patentably distinct Restriction Subgroups of the claimed invention. Under PCT Rule 13.3, the determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or *as alternatives within a single claim*.

Each of the nucleotide sequences comprise a patentably distinct subgroup. According to the Official Gazette (OG) of the Patent Office (Mar.27, 2007) (shortened):

> "The office has reconsidered the policy set forth in the 1996 Notice [i.e. up to ten, independent and distinct molecules described by the nucleotide sequence] in view of the changes in the complexity of applications filed, the types of inventions claimed and the state oft the prior art in this technology since that time. Because of these changes, the search and examination of up to ten molecules described by their nucleotide sequence often consumes a disproportionate amount of Office resources over that expended in 1996. Consequently, with this Notice the Office rescinds the partial waiver of 37 CFR 1.141 et seq. for restriction practice in national applications filed under 35 U.S.C. 111(a), and 37 CFR 1.475 et seq. for unity of invention determinations in both PCT international applications and the resulting national stage applications under 35 U.S.C. 371. This Notice is effective immediately and is applicable to all pending applications." As such, "claims to polynucleotide molecules will be considered for independence, relatedness, distinction, and burden as for claims to any other type of molecule."

As such, applicant is required under PCT Rule 13.3 to elect a single disclosed Subgroup as follows for prosecution on the merits to which the claims shall be restricted. In the event a particular Group is elected above, the applicant must further elect as follows:

a. Group I - one sequence from CML 1-190.

b. Group II - one sequence from CML 191-296.

c. Group III - one sequence from CML 1-190.

d. Group IV - one sequence from CML 191-296.

e. Group V - one sequence from CML 1-190.

f. Group VI - one sequence from CML 191-296.

g. Group VII - one sequence from CML 1-190.

h. Group VIII - one sequence from CML 191-296.

i. Group IX - two sequences from CML 1-296.

j. Group X - one sequence from CML 1-296.

k. Group XI - two sequences from CML 1-296.

l. Group XII - one sequence from CML 1-190.

m. Group XIII - one sequence from CML 1-190.

n. Group XIV - one sequence from CML 1-190.

o. Group XV - one sequence from CML 1-190.

p. Group XVI - one sequence from CML 191-296

q. Group XVII - one sequence from CML 191-296.

r. Group XVIII - one sequence from CML 1-190.

s. Group XIX - one sequence from CML 1-190.

Applicant is advised that a reply to this requirement must include an identification of the restriction subgroup that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election. Should applicant traverse on the ground that the Restriction Subgroups are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the Restriction Subgroups to be obvious

variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product

claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Molly E. Baughman whose telephone number is (571)272-4434. The examiner can normally be reached on Monday-Friday 8-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kenneth R Horlick/
Primary Examiner, Art Unit 1637

/Molly E Baughman/
Examiner, Art Unit 1637